

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in November 2002.

New Approvals

ANADA Number: 200-069

Pioneer Product: 098-379
Trade Name: Fertelin™ Sterile Solution
Ingredients: Gonadorelin diacetate tetrahydrate
Sponsor: Phoenix Scientific, Inc.
Approval Date: August 26, 2002
Status: Prescription only
Route: Intravenous or intramuscular
Species: Dairy cattle
Drug Form: Liquid (solution)
Concentration: 50 micrograms per milliliter
Indications: For the treatment of ovarian (follicular) cysts.
Tolerance: Not established.
Withdrawal: Not established.

21CFR 522.1078

NADA Number: 141-203

Trade Name: Deramaxx™ Chewable Tablets
Ingredients: Deracoxib
Sponsor: Novartis Animal Health US, Inc.
Approval Date: August 21, 2002
Status: Prescription only
Route: Oral
Species: Dogs (4 pounds and up)
Drug Form: Tablet (chewable)
Concentration: 25 and 100 milligrams per tablet
Indications: For the control of postoperative pain and inflammation associated with orthopedic surgery.
Patent Number: 5,521,207 Expiration date: November 30, 2013
Exclusivity: 5 years

21CFR 520.538

Change of Sponsor Name and Address

From: Fort Dodge Animal Health, Division of American Home Products Corp.

To: Fort Dodge Animal Health, Division of Wyeth
500 Fifth St. NW.
Fort Dodge, IA 50501
Drug labeler code: 000856

Actions Taken by FDA Center for Veterinary Medicine

Change of Sponsor

| | | | | |
|---------------------|----------------|----------------|----------------|----------------|
| NADA Number: | 034-879 | 038-838 | 045-715 | 091-065 |
| | 093-105 | 098-640 | 101-777 | 106-111 |
| | 136-651 | 141-003 | 141-004 | 141-005 |

From: A.H. Robins Co.

To: Fort Dodge Animal Health, Division of Wyeth
500 Fifth St. NW.
Fort Dodge, IA 50501
Drug labeler code: 000856

Suitability Petition Action

Number: 02P-0474/CP1
Sponsor: Phoenix Scientific, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug tiamulin hydrogen fumarate which differs from the pioneer product, Denagard™ (tiamulin) Soluble Antibiotic, Boehringer Ingelheim Vetmedica, Inc., NADA 134-644, by the following characteristics: The generic product will contain 45% tiamulin, as tiamulin hydrogen fumarate, whereas the pioneer contains 45% tiamulin hydrogen fumarate.

Action: Filed October 31, 2002.

Number: 02P-0084/CP1
Sponsor: Pharmaceutical Solutions, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug trimethoprim and sulfadiazine which differs from the pioneer product, Tribissen® 400 Oral Paste, Schering-Plough Animal Health Corp., NADA 131-918, by the following characteristics: The generic product will consist of a different dosage form (solution), different method of administration (via stomach tube), and different strength from the pioneer.

Action: Approved on November 7, 2002.

Number: 02P-0189/CP1
Sponsor: Phoenix Scientific, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug praziquantel which differs from the pioneer product, Droncit®, Bayer Corp., NADA 111-798, by the following characteristics: The generic product will consist of a different dosage form (solution) from the pioneer.

Action: Approved on November 7, 2002.

Number: 02P-0198/CP1
Sponsor: Richdel, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will consist of a different dosage form (gel) from the pioneer.

Action: Approved on November 7, 2002.